K033955

B. RTIST 510(K) SUMMARY

Date: 17th December, 2003

Submitters Name: Mirada Solutions Ltd.
Submitters Address: Level 1, 23-28 Hythe Bridge Street, Oxford OX1 2ET.
Submitters Contact: Michelle Sawyer, VP Regulatory Affairs.
Tel: 44-1865-265 500 Fax: 44-1865-265 501

Submitters Contact USA: Maria Ebio; Regulatory Affairs Manager
CTI Molecular Imaging, Inc. 810 Innovation Drive
Knoxville, TN 37932
Phone: 865-218-2534Fax: 865-218-3019

Device Proprietary Name: RTist
Common Name of Device: Multi-modality Registration Workstation Software
Classification Name: Class II: Picture Archiving and Communications System (892.2050) Product Code: **LLZ Image Processing System**

Critical Definitions:

Image Registration	The alignment of one or more [medical] images to a reference image in order to facilitate geometric comparison. This is a numerical operation that results in the computation of an explicit mathematical transformation between every point in the registered image sets.
Image Fusion	Registration forms the basis of image fusion in the sense that the geometrical alignment of images is a prerequisite. The notion of "fusion" takes this a step further by considering how to visualize the content of different images representing the same object [organ, anatomical region, etc.]. Such techniques include the use of overlays, semi-transparent renderings, etc.
ROI	Region of interest.

Note: In the context of this application, the term "registration" and "fusion" may be used interchangeably to describe geometric alignment of images and subsequent visualization.

Device description:

The RTist is a software application acting as a stand alone Picture Archiving and Communication System (PACS). It may be marketed as the software only as well as packaged with a standard 'off the shelf' PC Hardware. It is in effect a 'plug in' application to the Fusion 7D/ Miraview / Reveal – MVS software platform (reference K020546) but is effectively 'vendor' neutral and as such an enhancement to many other medical image/ data management systems.
The comprehensive array of features provided by the software allows the medical professional to visualize, review, interpret, manipulate, render and distribute medical image data stored in DICOM format. The networking component of the product allows the exchange of medical image data with any other DICOM-compatible or FTP-compatible server over a standard TCP/IP network.

The RTist receives images in DICOM format, which are then converted into volume data format using core software technology. The RTist viewer provides interactive orthogonal and multi-planar reformatting which enables the user to evaluate abnormality or malformation displayed in the image. The volume and linear measurement features provided by the software enable evaluation and quantification of region of interest volume, linear measurements and location/displacement.
The software also supports interactive segmentation of the region of interest (ROI), automated contouring of multi-slice ROI and labeling of structure(s) during critical evaluation.
RTist processes an array of medical images including anatomical images (e.g. CT and conventional MRI), and functional images (e.g. SPECT and PET).

The RTist software incorporates standard visualization features to display the input DICOM data and the results of the registration operations.

Summary of features:

- orthogonal and any-plane slicing of the volumetric data
- whole and region of interest zooming,
- image panning,
- window and level controls,
- image overlays for which the transparency, threshold and color map is user controlled.
- image interpolation
- 2D contour
- seed point contouring
- 3D volume contours

- automated contouring of multi-slice ROI's
- interpreted type labeling, annotations and messaging
- DICOM RTSS format (Standard RT Structure Set format) export
- contour dilation

Intended Use:
RTist is a software application, intended to display and visualize 2D & 3D multimodality (i.e. CT, MRI, and PET) medical image data. The user may process, render, review, store, print and distribute DICOM 3.0 compliant medical image data within the system and/or across computer networks at distributed locations utilizing standard PC hardware.
The volume and linear measurement functions are intended for evaluation and quantification of tumor measurements, location/displacement study, analysis and evaluation of both hard and soft tissues. The software also supports interactive segmentation of the region of interest (ROI), automated contouring of multi-slice ROI and labeling of 'avoidance' structure(s) during critical evaluation.
Typical users of this system are trained professionals, including but not limited to radiologists, clinicians and technicians. When interpreted by a trained physician, reviewed images may be used as an element for diagnosis.

Predicate Devices:

510(k) No.	Trade name	Manufacturer	Component Applicable to
K013878	Cybermed v-works.	Cybermed Inc.,	Technological characteristics
K031013	Starpacs system	Infintt Co., ltd.	Data management.
K032483	Viatronix V3D Explorer	Viatronix Inc.	Technological characteristics.
K030457	Rex, version 3.0	Pointdx, Inc.,	Technological characteristics.
K992654	Plug n' view 3D	Voxar Ltd.	Technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 17 2004

Mirada Solutions Ltd
% Ms. Maria Ebio
Regulatory Affairs Manager
CTI Molecular Imaging, Inc.
810 Innovation Drive
KNOXVILLE TN 37932

Re: K033955
Trade/Device Name: RTist
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: December 17, 2003
Received: January 6, 2004

Dear Ms. Ebio:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

FDA INDICATION FOR USE FORM

Ver/ 3 - 4/24/96

Applicant: Mirada Solutions Ltd.

510(k) Number (if known): K033955

Device Name: RTist

Indications for Use:
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PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over – The – Counter Use__

(Per 21 CFR 801.109)

(Per 21 CFR 801.109) (Optional Format 1-2-96) Truthful and Accurate Statement

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033955